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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,525	02/05/2004	David Edwards	000166.0109-US03	2889
26853	7590	01/11/2005	EXAMINER	
COVINGTON & BURLING ATTN: PATENT DOCKETING 1201 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20004-2401			WEISS JR, JOSEPH FRANCIS	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/771,525

Applicant(s)

EDWARDS ET AL.

Examiner

Joseph F. Weiss, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/05/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindahl et al (WO96/16687).

In regards to claim 1, Lindahl discloses an indicating device (Figs 1-9) comprising a casing (Maneuver unit A or B or both), a body disposed within the casing (1) reversibly moveable between a first position and a second position, an indicator (2) reversibly moveable between a rest position and an indicating position and a means for coupling the body and the indicator (page 8 lines 5-13), wherein upon a first movement of the body from the first position to the second position the means for coupling couples the body and the indicator, and upon a second movement of the body from the second position to the first position the indicator moves from the rest position to the indicating position.

In regards to claim 2, Lindahl discloses that upon a subsequent movement of the body from the first position to the second position the body and the indicator remain coupled and the indicator moves from the indicating position to the rest position, and upon a subsequent movement of the body from the second position to the first position

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the body and the indicator remain coupled and the indicator moves from the rest position to the indicating position.

In regards to claim 3, Lindahl discloses the indicator makes an audible click when the means for coupling couples the body and the indicator. (Page 11, lines 13-20)

In regards to claim 4, Lindahl discloses the indicator as disposed in the casing.

In regards to claim 5, Lindahl discloses a portion of the indicator is outside of the casing when the indicator is in the indicating position.

In regards to claim 6, Lindahl discloses indicator comprises a ring disposed between the casing and the body. (9)

In regards to claim 7, Lindahl discloses wherein the means for coupling comprises a lip (unlabeled notched edge of 2 & 4/30) coupled to the indicator and a flange (unlabeled matching notched edge of 1 and 3/32) coupled to the body for engaging the lip.

In regards to claim 8, Lindahl discloses the flange comprising a ratchet surface so that the lip remains locked with the flange once the flange engages the lip. (the notches).

In regards to claim 9, Lindahl discloses the means for coupling further comprises a stop coupled to the body for coupling the lip between the stop and the flange. (The matching reverse notches on the interior of 9)

In regards to claim 10, Lindahl discloses a means for decoupling the body and the indicator. (Locking ring 9, see page 7 line 28 to page 8 line 3).

In regards to claim 11, Lindahl discloses the means for decoupling is configured so that applying an axial force to the indicator disengages the flange from the lip.
(Locking ring 9, see page 7 line 28 to page 8 line 3).

In regards to claim 12, Lindahl discloses the means for decoupling comprises a knob coupled to the indicator. (Cap of the inhaler serves as a knob, see page 7 line 28 to page 8 line 3).

In regards to claim 13, Lindahl discloses a device for emitting powder comprising an indicating device of claim 1. (See fig 10 & supporting text).

In regards to claim 14, Lindahl discloses that its indicating device indicates the device is ready for use when the indicator is in the indicating position. (it lets you know a dose is ready to be inhaled).

In regards to claim 15, as set forth in the rejection to claims 1 & 7 which is herein incorporated by reference Lindahl discloses an indicating device comprising a casing, a body disposed within the casing and reversibly moveable between a first position and a second position, an indicator reversibly moveable between a rest position and an indicating position, a lip coupled to the indicator; and a flange coupled to the body for engaging the lip; wherein the flange engages the lip upon a first movement of the body from the first position to the second position, and wherein the engagement of the flange to the lip causes the indicator to move from the rest position to the indicating position upon a second movement of the body from the second position to the first position.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindahl et al.

In regards to method claims 33-36, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 1-15.

5. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindahl as applied to claims 1-15 above the rejection of which is herein incorporated by reference in regard to all the limitations of the indicator, and further in view of Ambrosio et al (US 6240918).

Lindahl substantially discloses the instant application's claimed invention to include all limitations directed toward an indicator set forth in claims 16-32 which are the same as those set forth in claims 1-15 & which were rejected under 35 USC 102 as noted above and which is herein incorporated by reference and furthermore discloses the use of the indicator in a casing/dry powder inhaler with a powder emitting aperture (See fig 10) as defined by a hemispheric region (note the aperture at the end of B closest to the Fig 10 label) and a second casing (A) within which the body can be

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disposed (page 7 lines 10-15) and which would inherently possess a chamber defined by a straight wall of circular cross section & a proximal & distal end (this inherency is based upon the fact the inhaler structure depicted is circular in cross section & needs to have some sort of interior chamber to facilitate the passage of powdered medicament through it and of an elongated shape) but does not explicitly disclose a cylindrical chamber with the noted features that also has a ring circumferentially coupled to an inner surface of said chamber. However, Ambrosio discloses such (Note annular ring 422 & chamber defined by 440 see fig 4 & figs 46A-49). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Ambrosio and used them with the device of Lindahl. The suggestion/motivation for doing so would have been because Lindahl discloses the use of his dose indicator with long cylindrical coming dry powder inhalers & Ambrosio is such a type of an inhaler that discloses use of a indicator with its inhaler (note the disclosure of a counter/indicator in base 300/320). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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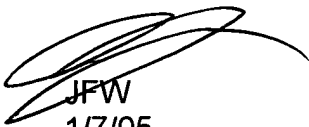
Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6766799, 6761161, 6732732, 6729330, 6336453, 6328037, 6076521, 5421482

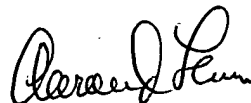
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Weiss, Jr. whose telephone number is (571) 272-4805. The examiner can normally be reached on Monday through Friday from 8 am until 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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1/7/05


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